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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/715,547

11/19/2003

Alexander Levitzki

27148

5591

67801

7590

09/29/2008

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EXAMINER

TRUONG, TAMTHOM NGO

ART UNIT

PAPER NUMBER

1624

MAIL DATE

DELIVERY MODE

09/29/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/715,547

**Applicant(s)**

LEVITZKI ET AL.

**Examiner**

TAMTHOM N. TRUONG

**Art Unit**

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 7-8-08 (RCE).  
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5 and 9-34 is/are pending in the application.  
4a) Of the above claim(s) 4, 5, 12-27 and 32-34 is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 1, 9, 28 and 29 is/are rejected.  
7) ☒ Claim(s) 2, 3, 10, 11, 30 and 31 is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_  
5) ☐ Notice of Informal Patent Application  
6) ☐ Other: \_\_\_\_\_

**NON-FINAL ACTION**

***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(c), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(c) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7-8-08 has been entered.

Claims 6-8 have been cancelled.

Claims 4, 5, 12-27 and 32-34 are withdrawn.

Claims 1-3, 9-11 and 28-31 are pending.

The amended claims 1 and 21 have overcome the previous rejections of 112/1<sup>st</sup> and 2<sup>nd</sup> paragraphs by not having R<sub>2</sub> as a pair of electrons.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

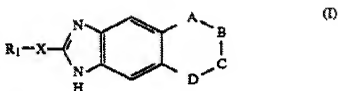
Claims 1 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Mertens et. al.** (US 4,954,498 – cited previously).

In column 14, the compound of Example 2a is a derivative of a compound of the instant formula II with the following substituents:

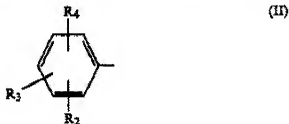
- i. R<sub>1</sub> is hydrogen;
- ii. R<sub>3</sub>, R<sub>5</sub>, R<sub>7</sub> – each is a pair of electrons;
- iii. R<sub>4</sub> is hydrogen;
- iv. R<sub>2</sub> is a substituted aryl group (note the instant disclosure allows substitution on the aryl group);
- v. R<sub>8</sub> is hydrogen;

The reference's compound differs from the claimed compound by having an *oxo* group at the 8-position

However, in column 2, the definition of A, B, C, D allows for an unsubstituted 8-position as well, see the following excerpt:



wherein  $R_1$  is a phenyl radical of the general formula:



methyl or alkylcarbonylaminoalkyl radical, X is a valency bond, an alkylene or vinylene radical, an imino group ( $-\text{NH}-$ ) or an amide group ( $-\text{CONH}-$ ) and A, B, C and D, independently of one another, are carbon and nitrogen atoms which can be substituted by hydrogen atoms or alkyl or cycloalkyl radicals, whereby the carbon atoms can also carry hydroxyl or oxo groups or can be components of a 3 to 7 membered spirocycle, whereby the six-membered ring containing A, B, C and D can be saturated, partly unsaturated or unsaturated, the tautomers thereof and the physiologically acceptable salts thereof with inorganic and organic acids.

Note, the substituents on B correspond to the instant  $R_6$ , which can be an alkyl or a cycloalkyl group.

Thus, with the above equivalency teaching, the skilled chemist would have been motivated to modify the compound of Example 2a by removing the *oxo* group to obtain a compound of the instant formula II because such a compound would have been expected to lower blood pressure.

Note, the recent ruling in KSR determines obviousness based on what a skilled artisan would have known at the time of the invention, and on what such a person would have reasonably expected to have been able to do in view of that knowledge (*KSR, 82 USPQ 2d, 1385*). In other words, the decision in KSR forecloses the argument that a **specific** teaching, suggestion, or motivation is required to support a finding of obviousness.

Therefore, at the time of the invention, it would have been obvious to select a compound as claimed herein in view of the teaching above.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 28 and 29 rejected under 35 U.S.C. 103(a) as being unpatentable over **Mertens et. al.** (US'498) in view of **Boschelli et. al.** (5,990,146).

The Example 2a of US'498 discloses a compound of substituted 7,8-dihydro-1H-imidazo[4,5-g]-quinazolin-8-one. The process of making the compound of Example 2a is analogous to Example 20 in column 21, which has the step of recrystallisation. However, it is silent to chromatography. Such a difference can be resolved by the teaching of **Boschelli et. al.** (US'146).

Boschelli generally describes a tricyclic system of fused benzimidazole. Boschelli also discloses chromatography as a step of purification in many examples (see Examples 7-9). Thus, clearly, using chromatography to separate or purify a compound is well known in the art. It would have been within the level of one skilled in the art to make a tyrphostin derivative disclosed by Mertens, and purify it by chromatography as taught by Boschelli.

Therefore, at the time of the invention, it would have been obvious to make and enrich a compound of formula II in view of the combined teachings above.

#### ***Claim Objections***

4. Claims 2, 3, 10, 11, 30 and 31 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Said claims recite a compound of formula II in which R<sub>6</sub> is an aryl group which is not taught or fairly suggested by the prior art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TAMTHOM N. TRUONG whose telephone number is (571)272-0676. The examiner can normally be reached on M, T and Th (9:00-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Tamthom N. Truong/

/James O. Wilson/  
Supervisory Patent Examiner, Art Unit 1623

***Tamthom N. Truong***  
***Examiner***  
***Art Unit 1624***